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a³
20. (Once Amended) A method for preparing a topical L-ascorbic acid composition, comprising micronizing ascorbic acid powder in an oil, wherein the resultant composition comprises greater than approximately 25% L-ascorbic acid, by weight.

REMARKS

The Applicant acknowledges receipt of the January 18, 2001 Office Action. In the Office Action, the Examiner rejected Claims 1-24 under 35 U.S.C. § 102(b), as being anticipated by PCT Publication WO 93/00015, to Kalamazoo Holdings, Inc. (hereinafter "Kalamazoo Holdings"). The Examiner also rejected Claims 1, 13-16, 18, 20, and 22 under 35 U.S.C. § 103(a), as being obvious over Kalamazoo Holdings. No other rejection was made. The Applicant respectfully requests that the Examiner reconsider and withdraw these rejections in view of the above amendments and the following remarks.

The Present Amendments

Independent Claims 1 and 20 and dependent claim 6 have been amended to more particularly point out the subject matter which the applicant regards as his invention, see 35 U.S.C. § 112, second paragraph. No new matter has been added by these amendments. For example, explicit support for these amendments may be found at page 2, line 12. Cf. Eiselstein v. Frank, 52 F.3d 1035, 34 USPQ2d 1467 (Fed. Cir. 1995) (support for term "about" may be found in the use of a whole number). All pending claims, as amended, are listed in the Appendix. See 37 C.F.R. § 121(c)(1)(ii) (2001).

The Rejections Under 35 U.S.C. § 102(b)

The Examiner has rejected Claims 1-24 under 35 U.S.C. § 102(b), as being anticipated by Kalamazoo Holdings. In support of this rejection, the Examiner asserts that Kalamazoo Holdings discloses a composition comprising micronized L-ascorbic acid particles, for the stabilization of essential oils, used in cosmetics which are topically applied. The Examiner cites seven passages in Kalamazoo Holdings: (i) page 1, lines 5-8; (ii) page 5, lines 16-28; (iii) page 6, lines 5-9; (iv) page 9, lines 21-27; (v) page 10, lines 15-18; (vi) page 11, lines 5-18, 24-26; and (vii) page 33, lines 9-25.

However, the invention *as claimed* is not anticipated by Kalamazoo Holdings and, more specifically, is not disclosed in the compositions and methods of the passages cited by the Examiner. Independent Claims 1, 20 and 24 are the only independent claims of the present

application. Each of these claims recites, either directly or indirectly, a composition for topical use "comprising greater than 25% L-ascorbic acid, by weight." Kalamazoo Holdings does not teach formulations for topical use containing a greater than 25% of ascorbic acid.

More specifically, three of the passages cited by the Examiner, passages (iii), (vi) and (v), relate only to the size of or methods of milling the ascorbic acid particle, see, e.g., page 6, lines 5-9; page 11, lines 5-26, or are directed to the carrier to be used, see page 10, lines 15-18. The remaining passages cited by the Examiner refer, sometimes in the abstract, to amounts of ascorbic acid, but require amounts in the range of about 0.001% to about 0.05%, by weight; no greater amount of ascorbic acid in a topical composition is disclosed. Specifically, passage (i) states that the amount needed to be an "effective antioxidant" is "at weight concentrations of 0.02% and even at 0.005% or below," some five hundred times lower than the approximate low threshold recited in Claims 1, 20 and 24. See page 1, lines 5-8. Similarly, passages (ii) and (vii) disclose only "0.001% or more by weight of ascorbic acid particles" and 0.05%¹ of micronized ascorbic acid, see page 5, lines 16-28; page 33, line 9-25, some 2500 times and five-hundred times lower than the approximate low threshold recited in Claims 1, 20 and 24.

Passage (iv) refers to "an oxidative protective amount of an antioxidant composition," without specifying the amount of ascorbic acid. However, throughout Kalamazoo Holdings, the "oxidation-protective amount" needed to stabilize a fat is disclosed in the range of 0.001% to 0.05%, orders of magnitude less than the approximate lower threshold of the pending claims. For example, Table 1, page 18, discloses that 0.05% is enough to be an oxidation-protective amount. Similarly, Table 2-1, page 19, discloses that a general range from 0.001% to 0.05% is sufficient to be an oxidation-protective amount. Moreover, the reference indicates that, to achieve an equivalent effect of other commonly used synthetic antioxidants, such as BHA and BHT) "less than 0.005% [micronized ascorbic acid] is needed, and even as low as 0.001% or 0.002% may be used." See page 20, lines 14-16. Thus, there is no disclosure of formulations for

¹ This recitation of "0.05%" may refer to the use of the pre-formed, milled ascorbic acid concentrate of Example 6. See pages 28-30. Because this milled concentrate is described as containing 26% ascorbic acid, by weight, in soy oil, the percentage of ascorbic acid in the cosmetic composition of Example 10 is more likely about 0.013%, by weight. For purposes of this Amendment only, however, Applicant will assume that Kalamazoo Holding discloses the higher amount of 0.05%. No concession is made for purposes of future prosecution.

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topical use containing greater than approximately 25% ascorbic acid. Accordingly, Applicant respectfully urges that the rejections under 35 U.S.C. § 102(b) are inappropriate. See, e.g., PPG Indus., Inc. v. Guardian Indus. Corp., 75 F.3d 1558, 37 USPQ2d 1618 (Fed. Cir. 1996) (“To anticipate a claim, a reference must disclose every element of the challenged claim and enable one skilled in the art to make the anticipating subject matter.”). In light of the above remarks, Applicant respectfully requests that the Examiner reconsider and withdraw the rejections of Claims 1-24 under 35 U.S.C. § 102(b).

Rejections Under 35 U.S.C. § 103(a)

The Examiner has also rejected Claims 1, 13-16, 18, 20, and 22 under 35 U.S.C. § 103(a), as being obvious over Kalamazoo Holdings. In support of this rejection, the Examiner again asserts that Kalamazoo Holdings discloses a composition comprising micronized L-ascorbic acid particles, for the stabilization of essential oils, used in cosmetics which are topically applied. Moreover, the Examiner asserts that “it would have been obvious to one of ordinary skill in the art to use any oil”. The Examiner again cites seven passages in Kalamazoo Holdings: (i) page 1, lines 5-8; (ii) page 5, lines 16-28; (iii) page 6, lines 5-9; (iv) page 9, lines 21-27; (v) page 10, lines 15-18; (vi) page 11, lines 5-18, 24-26; and (vii) page 33, lines 9-25, and relies on disclosure at page 30, lines 1-8, for the proposition that the choice of milling medium is not critical.

The claimed invention would not be obvious to a person of ordinary skill in the art. Even if Kalamazoo Holdings is assumed to be an analogous reference, and thus suitable for use in analyzing obviousness, it does not suggest the use of the much higher levels of ascorbic acid recited in the pending claims. Indeed, the reference teaches away from the claimed levels of ascorbic acid in a cosmetic composition. See, e.g., In re Sponnable, 405 F.2d 578, 587, 160 USPQ 237, 244 (CCPA 1969) (holding that cited references taught away because the combination of reference “would produce a seemingly inoperative device”). For example, at page 18, lines 17-20, Kalamazoo Holdings teaches that the ascorbic acid particles are “effective at unconventionally low dose levels, far below the standard 0.02% permissible dose levels of oil-soluble synthetic antioxidants.” Thus, there is no motivation or suggestion to use (much less, an enabling teaching to create) a topical formulation having higher levels of ascorbic acid. See ACS Hosp. Sys., Inc. v. Montefiore Hosp., 732 F.2d 1572, 221 USPQ 929 (Fed. Cir. 1984)

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("Obviousness cannot be established by combining the teachings of the prior art to produce the claimed invention, absent some teaching or suggestion supporting the combination.").

In fact, as noted above, Kalamazoo Holdings suggests the use minute levels of ascorbic acid. The dramatic difference between Kalamazoo Holdings and the pending claims arise from the distinct problems addressed. Kalamazoo Holdings only addresses, and thus only teaches, "oxidative-protection" of certain components in the certain formulations. Applicant, on the other hand, has addressed the distinct long-felt need for a cosmetic composition that will penetrate the skin and deliver relatively high levels of ascorbic acid.² See, e.g., U.S. Patent No. 5,140,043 at col. 2, lines. 49-52 ("[S]cientists working in the field have had difficulty in formulating stable solutions of ascorbic acid which would be useful for cosmetic, dermatologic, or ophthalmic needs. Nevertheless, because of the many beneficial pharmaceutical effects attributed to ascorbic acid, numerous attempts have been made to overcome these difficulties.").

In sum, then, it would not have been obvious, especially based solely on the minute oxidative-protective amounts of ascorbic acid taught in Kalamazoo Holdings, to make the claimed topical compositions or to perform the claimed methods. Accordingly, Applicant respectfully urges that the rejections under 35 U.S.C. § 103(a) are inappropriate. In light of these remarks, Applicant respectfully requests that the Examiner reconsideration and withdraw the rejections of Claims 1, 13-16, 18, 20, and 22 under 35 U.S.C. § 103(a).

CONCLUSION

Applicant respectfully asserts that the above-captioned application, in which Claims 1-24 remain pending, is fully in condition for allowance. The Applicants urge the Examiner to contact the undersigned if any questions remain as to the above-captioned application. Please charge any

² Accordingly, Kalamazoo Holdings is not "from the same field of endeavor," and is not "reasonably pertinent to the particular problem with which the [Applicant] is involved." In re Clay, 966 F.2d 656, 23 USPQ2d 1058 (Fed. Cir. 1992) (reversing obviousness rejection on ground that cited reference was not "analogous"). Accordingly, Applicant also asserts that Kalamazoo Holdings is not an analogous reference. For purposes of this Amendment only, however, Applicant will assume that Kalamazoo Holdings is analogous art. No concession is made for purposes of future prosecution.

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additional fees, including any fees for additional extension of time, or credit overpayment to
Deposit Account No. 11-1410.

Respectfully submitted,
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APPENDIX

PENDING CLAIMS:

1. **(Once Amended)** A composition for topical use comprising greater than approximately 25% L-ascorbic acid, by weight, and a non-aqueous carrier, wherein said composition has a pH of greater than that of skin.
 2. The composition of Claim 1, wherein said composition comprises greater than 25% micronized L-ascorbic acid by weight.
 3. The composition of Claim 2, wherein said L-ascorbic acid has a mean particle size of no greater than approximately 5 μm .
 4. The composition of Claim 2, wherein said L-ascorbic acid has a mean particle size of no greater than approximately 2 μm .
 5. The composition of Claim 2, wherein said L-ascorbic acid has a mean particle size between approximately 0.01 μm and 1 μm .
 6. **(Once Amended)** The composition of Claim 1, wherein said composition comprises greater [that] than 30% ascorbic acid.
 7. The composition of Claim 1, wherein said composition comprises, by weight, more L-ascorbic acid than D-ascorbic acid.
 8. The composition of Claim 1, wherein said composition comprises, by weight, more L-ascorbic acid than ascorbic acid derivatives.
 9. The composition of Claim 1, wherein said composition is essentially free of D-ascorbic acid, and is essentially free of ascorbic acid derivatives.
 10. The composition of Claim 1, wherein said composition has a pH of at least about 5.5.
 11. The composition of Claim 1, wherein said composition has a pH of at least about 6.0.
 12. The composition of Claim 1, wherein said composition has a pH of at least about 7.0.
 13. The composition of Claim 1, wherein said composition further comprises an enzymatic exfoliant.
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14. The composition of Claim 1, wherein said enzymatic exfoliant comprises papain.
15. The composition of Claim 1, wherein said non-aqueous carrier comprises glycerin.
16. The composition of Claim 1, wherein said L-ascorbic acid is micronized in oil.
17. The composition of Claim 16, wherein said oil may be derived from plant materials.
18. The composition of Claim 16, wherein said oil comprises capric/caprylic triglycerides.
19. The composition of Claim 2, wherein said L-ascorbic acid is prepared by a wet micronization process.
20. **(Once Amended)** A method for preparing a topical L-ascorbic acid composition, comprising micronizing ascorbic acid powder in an oil, wherein the resultant composition comprises greater than approximately 25% L-ascorbic acid, by weight.
21. The method of Claim 20, wherein said oil may be derived from plant materials.
22. The method of Claim 20, wherein said oil comprises capric/caprylic triglycerides.
23. A method of providing one or more of the following treatments to a mammal in need of such treatment: UV protection, removal and prevention of wrinkles, or stimulating collagen production in a mammal, comprising,
 - identifying a mammal in need of such treatment, and
 - topically applying the composition of Claim 1 to said mammal.
24. The method of Claim 23, wherein said mammal is a human.